

Chapter 5 510(k) Summary

SEP - 7 2011

510(k) Summary

Submitted by: Coreleader Biotech Co., Ltd.
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Contact Person: Teeming Tsao

Date Prepared: September 20, 2010

Proprietary Name: Coreleader Hemo-Pad

Common Name: Topical Hemostasis Pad

Classification: Unclassified

Classification Name: Topical Wound Dressing Pad

Predicate Device: Scion Cardio-Vascular, Inc., K032986, CLO-SUR^{PLUS}
P.A.D.
Perclose, Inc., K021062, ChitoSeal
T-Scientific, Inc., K030334, T-PAD

Device Description: The Coreleader Hemo-Fiber wound dressing is made from poly-D-glucosamine and poly-N-acetylglucosamine derived from chitosan. The Coreleader Hemo-Fiber is a soft, non-woven topical pad for hemostasis and wound care. The natural biological property of this material carries cation (positively charged ion) that helps to stop external hemorrhage, and the Coreleader Hemo-Fiber wound dressing absorbs the wound exudates to form a hydrogel protection layer while providing for an optimal wound-healing environment.

Chapter 5 510(k) Summary

Coreleader Hemo-Pad is a sterile topical hemostasis pad, packed in a foil pouch and sterilized by gamma-ray radiation to a 10^{-6} SAL.

Intended Use:

Coreleader Hemo-Pad is a dressing indicated for topical wound management and for the external topical temporary control of moderate to severe bleeding.

The dressing is indicated for the following wounds:

abrasions, lacerations, skin surface puncture sites for vascular procedures (arteries and veins)

Technological Characteristics:

Coreleader Hemo-Pad is a soft, non-woven topical pad made of poly-D-glucosamine and poly-N-acetylglucosamine derived from chitosan. The natural biological property of this material carries cation (positively charged ion) that helps to stop external hemorrhage and the gives the Coreleader Hemo-Pad an advantage as an effective bacterial barrier while providing for an optimal wound-healing environment. In addition, it has superb ventilation texture and high absorption ability that are compatible to human skin.

Besides, the safety and use of chitosan have been published by researchers over a period of decades. This formulation has many useful and advantageous properties in their application as a wound dressing, namely biocompatibility, biodegradability, hemostatic and anti-infectional activity.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Coreleader Biotech Co., Ltd.
% Mr. Ian Li
Regulatory Manager
19F, No. 100, Sec. 1, Santai 5th Road
Sijhih City, Taipei 25102
Taiwan

SEP - 7 2011

Re: K102944
Trade/Device Name: Coreleader Hemo-Pad
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 17, 2011
Received: August 30, 2011

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

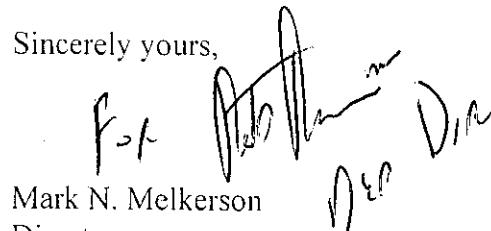
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director

Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Chapter 4 Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K102944

Device Name: Coreleader Hemo-Pad

Indications For Use:

Coreleader Hemo-Pad is a dressing indicated for topical wound management and for the external topical temporary control of moderate to severe bleeding.

The dressing is indicated for the following wounds:

abrasions, lacerations, skin surface puncture sites for vascular procedures (arteries and veins)

Prescription Use X

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan J Kline for MRM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page 1 of 1